Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1.-44. (Canceled)

45. (Currently amended) A composition [of] comprising a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

(a) between about 1% to about 15% of propofol;

(b) between about 1% to about [8%] 4% of a propofol-soluble diluent selected from a medium chain triglyceride comprising medium chain fatty acids of synthetic or natural origin, or mixtures of said medium chain triglycerides;

(c) between about 0.5% to about 5% of [a] one or more surface stabilizing amphiphilic ~~agent~~ agents; and

(d) from about 2.5% to about 20% of a pharmaceutically acceptable water-soluble polyhydroxy additive that acts as a tonicity modifier; and

(e) water;

~~(f) provided~~ wherein the ratio of propofol to diluent is about 1:4 to about 1:0.1 and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of from about ~~0.8 to about 15~~ greater than about 1.2 centipoise,

and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential. ~~prevents microbial growth, defined as no more than 0.5 log increase from the initial inoculum, of each of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans,* and *Aspergillus niger* for at least 7 days as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range 20-25°C, whereafter said aliquots are incubated at 20-25°C and are tested for viability of the microorganisms in the inoculated dispersion as determined by counting the colonies of said organism after 24, 48 hours and 7 days; and~~

~~results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight,~~

~~for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.~~

46. (Currently amended) The composition [of] according to claim 45, wherein the surface stabilizing agent is a surface modifier selected from the group consisting of ionizable phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

47. (Currently amended) The composition [of] according to claim 45, wherein the propofol-soluble diluent is selected from the group consisting of a synthetic fatty acid triglyceride, a natural fatty acid triglyceride, and mixtures thereof.

48. (Currently amended) The composition [of] according to claim 45, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:3 to about 1:0.5.

49. (Currently amended) The composition [of] according to claim 45, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:2 to about 1:1.

50. (Currently amended) The composition [of] according to claim 45, wherein the propofol-soluble diluent is a mixture of medium-chain triglyceride and vegetable oil.

51. (Currently amended) The composition [of] according to claim 50, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

52. (Currently amended) The composition [of] according to claim 45, wherein the composition contains about 2% to about 10% of propofol.

53. (Currently amended) The composition [of] according to claim 45, wherein the pharmaceutically acceptable water-soluble polyhydroxy additive provides the propofol-containing dispersion or composition with an osmolality of about 250 to about 700 milliosmolal.

54. (Currently amended) The composition [of] according to claim 53, wherein the osmolality is about 300 to about 500 milliosmolal.

55. (Currently amended) The composition [of] according to claim 45, wherein the viscosity is from about 2 to about 5 centipoise.

56. (Currently amended) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion being capable of inhibiting the growth of microorganisms and consisting essentially of (i) about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent selected from the group consisting of isopropyl myristate, cholesteryl oleate, ethyl oleate, squalene, alpha-tocopherol, and mixtures thereof; ~~, and~~ (ii) about 0.8% to about 4% of a surface stabilizing amphiphilic agent, said surface stabilizing amphiphilic agent selected from the group consisting of cholesterol, charged phospholipid of natural sources, uncharged phospholipid of natural sources, hydrogenated lecithin, synthetic phospholipids, anionic dimyristoylphosphatidyl glycerol in an amount of 0.05% to 0.25% by weight of the dispersion, egg lecithin in an amount of about 1% to 3% of the dispersion and a combination thereof, (iii) water; [,] and (iv) a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, the dispersion (i) having a viscosity of greater than about 1.2; (ii) being devoid of additional bactericidal or bacteriostatic preservative agents; and (iii) causing no irritation at the site of injection.

57. (Currently amended) The dispersion [of] according to claim 56, wherein the propofol and diluent are present in a ratio of about 1:4 to about 1:0.1 of propofol to diluent.

58. (Currently amended) The dispersion [of] according to claim 56, where the propofol and amphiphilic agent are present in a ratio of about 1:0.8 to about 1:2.5 of propofol to amphiphilic agent.

59. (Currently amended) The dispersion [of] according to claim 56, that has a viscosity of from about 0.8 to about 15 centipoise.

60. (Currently amended) The dispersion [of] according to claim 56, wherein the propofol-soluble diluent is selected from the group consisting of a pharmaceutically acceptable saturated

fatty acid triglyceride, a pharmaceutically acceptable unsaturated fatty acid triglyceride, and mixtures thereof.

61. (Currently amended) The dispersion [of] according to claim 56, wherein the propofol-soluble diluent is selected from the group consisting of pharmaceutically acceptable esters of medium chain fatty acids, pharmaceutically acceptable esters of long chain fatty acids, pharmaceutically acceptable triglycerides of medium chain fatty acids, and mixtures thereof.

62. (Canceled)

63. (Currently amended) The dispersion [of] according to claim 56, wherein the propofol-soluble diluent is a mixture of medium chain triglyceride and vegetable oil.

64. (Currently amended) The dispersion [of] according to claim 63, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

65. (Currently amended) The dispersion [of] according to claim 56, which contains about 2% to about 10% of propofol.

66. (Currently amended) The dispersion [of] according to claim 56, wherein the surface stabilizing amphiphilic agent is a surface modifier selected from the group consisting of ionizable phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

67. (Currently amended) The dispersion [of] according to claim 56, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of charged phospholipid of natural sources, uncharged phospholipid of natural sources, hydrogenated lecithin, a synthetic phospholipid, a poloxamer, a poloxamine, a polyoxyethylene sorbitan ester, and mixtures thereof.

68. (Canceled)

69. (Currently amended) The dispersion [of] according to claim 56, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of 1,2-dimyristoyl-sn-

glycero-3-phosphatidylcholine, 1,2-dimyristoyl-sn-glycero-3-[phospho-rac-(1-glycerol)], egg lecithin, egg phosphatidylcholine, soy phosphatidyicholine, saturated soy phosphatidylcholine, soy lecithin, dimyristoylphosphatidylcholine, and dimyristoylphosphatidylglycerol.

70. (Currently amended) The dispersion [of] according to claim 56 that elicits an anesthetic effect in a warm-blooded animal and human subject upon intravenous administration.

71. (Currently amended) The dispersion [of] according to claim 56, wherein the tonicity modifier is selected from the group consisting of sucrose, dextrose, trehalose, mannitol, lactose, glycerol, and mixtures thereof.

72. (Currently amended) The dispersion [of] according to claim 56 that is isotonic with blood.

73. (Currently amended) The dispersion [of] according to claim 56 that is unsuitable for intravenous injection.

74. (Currently amended) The dispersion [of] according to claim 56 that contains a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier in an amount so as to provide an osmolality of about 250 to about 700 milliosmolal.

75. (Currently amended) The dispersion [of] according to claim 74, wherein the osmolality is about 300 to about 500 milliosmolal.

76. (Currently amended) The dispersion [of] according to claim 56 that has a viscosity from about 2 to about 5 centipoise.

77. (Currently amended) The composition [of] according to claim 45, wherein propofol is present in an amount of about 2% to 5% by weight of the dispersion.

78. (Currently amended) The composition [of] according to claim 77, wherein propofol is present in an amount of about 2% by weight of the dispersion.

79. (Canceled)

80. (Currently amended) The composition [of] according to claim 45, wherein the polyhydroxy additive is mannitol.

81. (Currently amended) The composition [of] according to claim 80, wherein mannitol is present in an amount of about 5.5% by weight of the dispersion.

82.-86 (Canceled)

87. (Currently amended) The composition [of] according to claim [86] 45, wherein the medium-chain triglyceride is present in an amount of 4% by weight of the dispersion.

88. (Currently amended) The composition [of] according to claim [83] 45, wherein the mixture of medium-chain triglycerides is present in an amount of 4% by weight of the dispersion.

89. (Currently amended) The composition [of] according to claim 45, wherein the amphiphilic agent is egg lecithin.

90. (Currently amended) The composition [of] according to claim 89, wherein the egg lecithin is present in an amount of about 1% to about 7% by weight of the dispersion.

91. (Currently amended) The composition [of] according to claim 90, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion.

92. (Currently amended) The composition [of] according to claim 91, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion.

93. (Currently amended) The composition [of] according to claim 89, wherein the egg lecithin contains not less than 98% phosphatidylcholine.

94.-95. (Canceled)

96. (Currently amended) The composition [of] according to claim [95] 45, wherein the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

97.-98. (Canceled)

99. (Currently amended) The composition [of] according to claim [98] 45, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion and the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

100. (Currently amended) The composition [of] according to claim 45, wherein the pH of the composition is about 4 to about 9.

101. (Currently amended) The composition [of] according to claim 100, wherein the pH of the composition is about 5 to about 8.

102. (Currently amended) The composition [of] according to claim 45, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

103. (Currently amended) The composition [of] according to claim 45, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

104. (Currently amended) The composition [of] according to claim 102, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

105. (Previously presented) The composition according to claim 45, wherein the dispersion is steam sterilizable.

106. (Currently amended) The dispersion [of] according to claim 56, wherein propofol is present in an amount of about 2% to 5% by weight of the dispersion.

107. (Currently amended) The dispersion [of] according to claim 106, wherein propofol is present in an amount of about 2% by weight of the dispersion.

108. (Currently amended) The dispersion [of] according to claim 56, wherein the polyhydroxy tonicity modifier is present in an amount of 2.5% to about 20% by weight of the dispersion.

109. (Currently amended) The dispersion [of] according to claim 56, wherein the polyhydroxy tonicity modifier is mannitol.

110. (Currently amended) The dispersion [of] according to claim 109, wherein mannitol is present in an amount of about 5.5% by weight of the dispersion.

111. (Currently amended) The dispersion [of] according to claim 56, wherein the propofol-soluble diluent is a medium-chain triglyceride.

112. (Currently amended) The dispersion [of] according to claim 56, wherein the propofol-soluble diluent is a mixture of medium-chain triglycerides.

113. (Currently amended) The dispersion [of] according to claim 111, wherein the medium-chain triglyceride is a triglyceride of medium chain fatty acids of synthetic or natural origin.

114. (Currently amended) The dispersion [of] according to claim 111, wherein the medium-chain triglyceride is present in an amount of 2% to 6% by weight of the dispersion.

115. (Currently amended) The dispersion [of] according to claim 114, wherein the medium-chain triglyceride is present in an amount of 2% to 4% by weight of the dispersion.

116. (Currently amended) The dispersion [of] according to claim 115, wherein the medium-chain triglyceride is present in an amount of 4% by weight of the dispersion.

117. (Currently amended) The dispersion [of] according to claim 112, wherein the mixture of medium-chain triglycerides is present in an amount of 4% by weight of the dispersion.

118. (Currently amended) The dispersion [of] according to claim 56, wherein the amphiphilic agent is egg lecithin.

119. (Currently amended) The dispersion [of] according to claim 118, wherein the egg lecithin is present in an amount of about 1% to about 7% by weight of the dispersion.

120. (Currently amended) The dispersion [of] according to claim 118, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion.

121. (Currently amended) The dispersion [of] according to claim 120, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion.

122. (Currently amended) The dispersion [of] according to claim 118, wherein the egg lecithin contains not less than 98% phosphatidylcholine.

123.-124. (Canceled)

125. (Currently amended) The dispersion [of] according to claim [124] 56, wherein the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

126.-127. (Canceled)

128. (Currently amended) The dispersion [of] according to claim [127] 56, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion and the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

129. (Currently amended) The dispersion [of] according to claim 56, wherein the pH of the dispersion is about 4 to about 9.

130. (Currently amended) The dispersion [of] according to claim 129, wherein the pH of the dispersion is about 5 to about 8.

131. (Currently amended) The dispersion [of] according to claim 56, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

132. (Currently amended) The dispersion [of] according to claim 56, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

133. (Currently amended) The dispersion [of] according to claim 131, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

134. (Currently amended) The dispersion [of] according to claim 56, wherein the dispersion is steam sterilizable.

135. (Currently amended) The dispersion [of] according to claim 70, wherein the anesthetic effect comprises at least one of producing and maintaining ambulatory anesthesia, neurosurgical anesthesia, pediatric anesthesia, monitored anesthetic care, intensive care sedation, chronic sedation, general anesthesia, low dose sedation, and long-term sedation.

136. (Canceled)

137. (Currently Amended) A composition of a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm, the dispersion consisting essentially of:

(a) propofol in an amount of about 2% by weight of the dispersion;

(b) one or more [[a]] medium-chain ~~triglyceride~~ triglycerides in an amount of 4% by weight of the dispersion;

(c) egg lecithin in an amount of 1.6% by weight of the dispersion;

(d) anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion;

(e) mannitol in an amount of 5.5% by weight of the dispersion; and

(f) water.

138. (Canceled)

139. (Currently amended) The composition [of] according to claim 137, wherein the medium chain triglyceride is of synthetic or natural origin.

140. (Currently amended) The composition [of] according to claim 137, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

141. (Currently amended) The composition [of] according to claim 137, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

142. (Currently amended) The composition [of] according to claim 140, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

143. (Currently amended) The composition [of] according to claim 137, wherein the dispersion is steam sterilizable.

144. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

propofol in an amount of about 2% by weight of the dispersion;
a medium-chain triglyceride in an amount of 4% by weight of the dispersion;
egg lecithin in an amount of 1.6 % by weight of the dispersion;
anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and
mannitol in an amount of 5.5% by weight of the dispersion;
wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

145. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

propofol in an amount of about 2% by weight of the dispersion;
a mixture of medium-chain triglycerides in an amount of 4% by weight of the dispersion;
egg lecithin in an amount of 1.6 % by weight of the dispersion;
anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and
mannitol in an amount of 5.5% by weight of the dispersion;
wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

146. (Currently amended) The dispersion [of] according to claim 144, wherein the medium chain triglyceride is of synthetic or natural origin.

147. (Currently amended) The dispersion [of] according to claim 144, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

148. (Currently amended) The composition [of] according to claim 144, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

149. (Currently amended) The dispersion [of] according to claim 147, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

150. (Currently amended) The composition [of] according to claim 144, wherein the dispersion is steam sterilizable.

151. (New) A composition comprising a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

(a) propofol in an amount of from about 1% to about 15%;

(b) a lipophilic propofol-soluble diluent in an amount of up to about 4%;

(c) a surface stabilizing amphiphilic agent in an amount of between about 0.5% to about 5%;

(d) a pharmaceutically acceptable, water-soluble, polyhydroxy additive that acts as a tonicity modifier in an amount of from about 2.5% to about 20%; and

(e) water;

wherein the ratio of propofol to the diluent is about 1:4 to about 1:0.1 and the ratio of propofol to the amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of greater than about 1.2 centipoise; and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential.

152. (New) A composition comprising a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

(a) propofol in an amount of from about 1% to about 2%;

(b) a lipophilic propofol-soluble diluent in an amount of up to about 4%;

(c) a surface stabilizing amphiphilic agent in an amount of between about 0.5% to about 5%;

(d) a pharmaceutically acceptable, water-soluble, polyhydroxy additive that acts as a tonicity modifier; and

(e) water;

wherein the ratio of propofol to the diluent is about 1:4 to about 1:0.1 and the ratio of propofol to the amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of greater than about 1.2 centipoise; and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential.

153. (New) A composition comprising a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

(a) propofol in an amount of from about 10% to about 15%;

(b) a lipophilic propofol-soluble diluent in an amount of up to about 10%;

(c) a surface stabilizing amphiphilic agent in an amount of between about 0.5% to about 5%;

(d) a tonicity modifier selected from mannitol, trehalose, glycerol, sucrose, dextrose, lactose, or mixtures thereof; and

(e) water;

wherein the ratio of propofol to the diluent is about 1:4 to about 1:0.1 and the ratio of propofol to the amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of greater than about 1.2 centipoise; and further wherein the dispersion inhibits microbial growth, is non-irritating at the site of injection and decreases hemolytic potential.

154. (New) The composition according to claim 152, wherein the tonicity modifier is present in the dispersion in an amount of about 2.5% to about 20%.

155. (New) The composition according to claim 153, wherein the tonicity modifier is present in the dispersion in an amount of about 2.5% to about 20%.

156. (New) The composition according to claim 151, wherein the water-soluble, polyhydroxy additive is selected from mannitol, trehalose, glycerol, sucrose, dextrose, lactose, or mixtures thereof.

157. (New) The composition according to claim 152, wherein the water-soluble, polyhydroxy additive is selected from mannitol, trehalose, glycerol, sucrose, dextrose, lactose, or mixtures thereof.

158. (New) The composition according to claim 154, wherein the tonicity modifier is glycerol.

159. (New) The composition according to claim 158, wherein the tonicity modifier is present in an amount of bout 2.5%.

160. (New) The composition according to claim 45, wherein said composition prevents microbial growth, defined as no more than 0.5 log increase from the initial inoculum, of each of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans,* and *Aspergillus niger* for at least 7 days as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range 20-25°C, whereafter said aliquots are incubated at 20-25°C and are tested for viability of the microorganisms in the inoculated dispersion as determined by counting the colonies of said organism after 24, 48 hours and 7 days; and

results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight, for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.